



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/901,484	07/09/2001	Daniel Cohen	GEN-T111XC3D2	6608

23557 7590 12/08/2003

SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
2421 N.W. 41ST STREET
SUITE A-1
GAINESVILLE, FL 326066669

EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
----------	--------------

1634

DATE MAILED: 12/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/901,484

Applicant(s)

COHEN ET AL.

Examiner

Jeffrey Fredman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 4-10, 19-37 and 39-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 11-18 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-4, 9, 11-18 and 38 and SEQ ID NO: 179 in the paper filed October 8, 2003, is acknowledged. Since claims 4 and 9 are not drawn to SEQ ID NO: 179, they are withdrawn, along with claims 5-8, 10, 19-37 and 39-49 drawn to non-elected groups.

Priority

2. The current application claims priority to a series of cases dating back to 1997. However, the claims are not given priority to applications 08/996,306 and 60/099,658 because in the current application SEQ ID NO: 179 is 56,520 nucleotides while in those parent applications, the largest sequences were 56,516 nucleotides. Consequently, there is no possibility that these applications provide full descriptive support for SEQ ID NO: 179, and priority to these applications is denied. Therefore, for purposes of prior art, the priority date of this application is limited to 09/218,207, filed December 22, 1998, which provides the full 56,520 nucleotides of SEQ ID NO: 179.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-3, 11-18 and 38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims encompass a genus of nucleic acids which are different from those disclosed in the specification. The genus includes variants for which no written description is provided in the specification. This large genus is represented in the specification by only the particularly named SEQ ID No: 179. Thus, applicant has express possession of only SEQ ID NO: 179, in a genus which comprises hundreds of millions of different possibilities, due to the fragment language. Here, no common element or attributes of the sequences are disclosed as required in the fragments, not even the presence of certain domains. No functional limitation is imposed on the nucleic acid sequences. Further, these claims encompass alternately spliced versions of the proteins, allelic variants including insertions and mutations, inactive precursor proteins which have a removable amino terminal end, and only the specific nucleic acid sequence of SEQ ID NO: 179 has been provided. No written description of alleles, of

upstream or downstream regions containing additional sequence, or of alternative splice variants has been provided in the specification.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

"A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers*, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing *Amgen*). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition of fragments of SEQ ID NO: 179 lacks any specific structure. This definition, any fragment of 10 nucleotides of a PG1 gene (for example), without any structural information whatsoever, is precisely the situation of naming a type of material which is generally known to likely exist, but, except for the SEQ ID NO: 179, is in the absence of knowledge of the material composition and fails to provide descriptive support for the generic claim.

It is noted that in *Fiers v. Sugano* (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred,

Art Unit: 1634

that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of the compound solely by its name or fragments of SEQ ID 179, without any definition of the particular fragments claimed.

In the instant application, SEQ ID NO: 179 is described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which comprise SEQ ID NO: 179. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Genbank Accession No. H061164 (June 21, 1995).

Query: 50247 ttaattccaaattaagtatcaagaagactttaccatcaatggtgatcttaagtggtttga
50306

Query: 50307 ctgcaggcatgcttatgaccgatgctggaaggaagctgtatgtgaacacctggatatatg
50366

Query: 50367 gaaccctacttggctgcctgtgggttactattaaagcatagacaagtagctgtctccaga
50426

Query: 50427 cagtgggatgtgctacattgtctatTTTTTggcggctgcacatgacatcaaattgtttcct
50486

Query: 50487 gaatttattaaggagtgtaaataaagccttggtgattgaagattggataatagaatttgt
50546

Query: 50547 gacgaaagctgatatgcaatggtctt-gggcaaacatacct-ggttgtacaacttttagca
50604

Query: 50605 tcggggctgctgg--aagggtaaaagc-taaat-ggagtttctcc 50645

With regard to claim 2, H061164 is a human sequence (see organism subheading of Genbank record).

With regard to claim 11, the vector is Lafmid BA (see vector subheading of Genbank record).

With regard to claim 12, the host cell is DH10B (see lab host subheading of Genbank record).

5. Claims 1-3, 11, 12 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Genbank Accession No. R96921 (September 11, 1995).

Genbank Accession No. R96921 teaches an isolated polynucleotide sequence which has a region 100% match with 159 contiguous nucleotides of SEQ ID NO: 179 in the region from nucleotides 52376 to 52645 of SEQ ID NO: 179.

Sbjct: 274 ctcacaaanggtcctataaaatacagncggttgaaaaaaattttgtatcaaaatgttttg 215

Sbjct: 214 |||||
aaaattagaagccttctccctaacctgtattgatactgacttgcaattattttcctaaaat 155

Sbjct: 154 taagagccgtatacctacctgtaagtcttttcacatatcatttaaacttttgtttgatt 95

Sbjct: 94 attactgatttacagcttagttattaattttctttataagaatgccgtcgaatgtgcattg 35

Sbjct: 34 cttttatgtttttcagaaaagggtgtgttttggat 1

With regard to claim 2, R96921 is a human sequence (see organism subheading of Genbank record).

With regard to claim 3, the alignment above shows the fragment of greater than 10 nucleotides of SEQ ID NO: 179.

With regard to claim 11, the vector is pT7T3D (see vector subheading of Genbank record).

With regard to claim 12, the host cell is DH10B (see lab host subheading of Genbank record).

With regard to claim 38, R96921 teaches a polynucleotide sequence which comprises 12 nucleotides between 52626 and 52645 as shown in the alignment above.

6. Claims 1-3, 11, 12 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Genbank Accession No. N39909 (January 22, 1996).

Genbank Accession No. N39909 teaches an isolated polynucleotide sequence which has a region 100% match with 399 contiguous nucleotides of SEQ ID NO: 179 in the region from nucleotides 50287 to 50814 of SEQ ID NO: 179.

Query: 50287 gttgatcttaagtggtttgactgcaggcatgcttatgaccgatgctggaaggaagctgta
50346

Sbjct: 1 gttgatcttaagtggtttgactgcaggcatgcttatgaccgatgctggaaggaagctgta 60

Query: 50347 tgtgaacacctggatatatggaaccctacttggctgcctgtgggttactattaaagcata
50406

Sbjct: 61 |tgtgaacacctggatatatggaaccctacttggtgcctgtgggttactattaaagcata 120

Query: 50407 gacaagtagctgtctccagacagtgggatgtgctacattgtctatTTTTTggcggctgcac
50466

Sbjct: 121 |
gacaagtagctgtctccagacagtgggatgtgctacatttgtctatnttttggcggctgcac 180

```
Query: 50467 atgacatcaaattgtttcctgaatttattaaggagtgtaaataaagccttggtgattgaa
50526
      |||
Sbjct: 181 atgacatcaaattgtttcctgaatttattaaggagtgtaaataaagccttggtgattgaa 240

Query: 50527 gattggataatagaatttgtgacgaaagctgatatgcaatggctctgggcaaacatacct
50586
      |||
Sbjct: 241 gattggataatagaatttgtgacgaaagctgatatgcaatggctctgggcaaacatacct 300

Query: 50587 gggtgtacaacttttagcatcggggctgctggaagggtaaaagctaaatggagtttctcct
50646
      |||
Sbjct: 301 gggtgtacaacttttagcatcggggctgctggaagggtaaaagctaaatggagtttctcct 360

Query: 50647 gctctgtccatttcctatgaactaatgacaactt-gagaaggctgggaggattgtgtatt
50705
      |||
Sbjct: 361 gctctgtccatttcctatgaactaatgacaacttggagaaggctgggaggattgtgtatt 420

Query: 50706 ttg-caagtcagatggctgcatttttgag-cattaatttg-cagcgtatttcactttttc
50762
      |||
Sbjct: 421 ttgccaaagtcagatggctgcatttttgagccattaatttgccagcgtatttcacttttnc 480

Query: 50763 t-gttattttcaattt-attacaacttgacagct-ccaagctcttattactaaag 50814
      |||
Sbjct: 481 tggtaatttncaatttaattacaacttgacagctcccaanctcttaatacctaaag 535
```

With regard to claim 2, N39909 is a human sequence (see organism subheading of Genbank record).

With regard to claim 3, the alignment above shows the fragment of greater than 10 nucleotides of SEQ ID NO: 179.

With regard to claim 11, the vector is pT7T3D (see vector subheading of Genbank record).

With regard to claim 12, the host cell is DH10B (see lab host subheading of Genbank record).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Genbank Accession No. N39909 (January 22, 1996) in view of Capecchi et al (Science (1989) 244:1288-1292).

Genbank Accession No. N39909 teaches an isolated polynucleotide sequence which has a region 100% match with 399 contiguous nucleotides of SEQ ID NO: 179 in the region from nucleotides 50287 to 50814 of SEQ ID NO: 179 as shown in the alignment above.

Genbank Accession No. N39909 does not teach formation of a disrupted host mammalian cell.

Capecchi teaches the use of homologous recombination to form host cells and mammals (see page 1280, figure 1, for example).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to screen Genbank Accession No. N39909 for its functional activity using the homologous recombination method of Capecchi since Capecchi states "Targeted disruption of these genes may not only reveal the phenotypes associated with inactivation of the individual genes, but through epistasis and molecular analyses, may also help define the developmental network controlling early mouse morphogenesis (see page 1292, column 1)." Thus, an ordinary practitioner, interested in identifying what phenotype is associated with the sequence of Genbank Accession No. N39909 would have been motivated by Capecchi to use targeted disruption in order to define the phenotype of the gene with which N39909 is associated.

10. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Genbank Accession No. N39909 (January 22, 1996) in view of Schena (PNAS (1996) 93:10614-10619).

Genbank Accession No. N39909 teaches an isolated polynucleotide sequence which has a region 100% match with 399 contiguous nucleotides of SEQ ID NO: 179 in the region from nucleotides 50287 to 50814 of SEQ ID NO: 179 as shown in the alignment above.

Genbank Accession No. N39909 does not teach labels or attachment to a solid support.

Schena teaches the attachment of ESTs to solid supports and labeling of the nucleic acids (see abstract and page 10614, column 2).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to place the EST of Genbank Accession No. N39909 onto a labeled array such as that of Schena since Schena states "The availability of large numbers of ESTs provide a rich resource of human cDNA clones for microarraying. (see page 10619, column 1)". Schena continues "This capacity, coupled with detailed biochemical analyses of the individual gene products, would greatly speed the functional analysis of the human genome (see page 10619, column 1)." An ordinary practitioner would have been motivated to place EST N39909 onto the microarray of Schena since Schena expressly suggests application of the microarray to known ESTs in order to rapidly analyse the function of the EST and determine its role in the human genome.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is currently 703-308-6568. In mid January, 2004, when TC 1600 relocates to the new USPTO facility in Alexandria, the examiner's phone number will become 571-272-0742. The examiner can normally be reached on 6:30-4:00.

Art Unit: 1634

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The supervisor's new telephone number in mid January will be 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is currently 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'Jeffrey Fredman', with a long horizontal flourish extending to the right.

Jeffrey Fredman
Primary Examiner
Art Unit 1634